

March 21, 2017

Urgent Field Safety Notice

Affected Product: VERSAJET[®] II Hydrosurgery System Console
FSCA reference: WR-2017-01
FSCA action: Device Modification/Exchange
Details of affected product: See below

Dear Customer,

This letter is to inform you of a voluntary Field Safety Corrective Action (FSCA) which affects a limited number of consoles for the VERSAJET[®] II Hydrosurgery System (the VERSAJET System), manufactured by Smith & Nephew Inc. USA and Smith & Nephew Medical, United Kingdom. This FSCA requires device modification/exchange in order to ensure compliance of a component in the affected consoles with the European Directive for Restriction of Certain Hazardous Substances (RoHS). Affected devices do not present any safety risks to patients.

Background

Directive 2011/65/EU (the RoHS directive) requires that certain medical device Electrical and Electrical Equipment (EEE) placed on the market after July 22, 2014 complies with restrictions on a number of hazardous substances.

Smith & Nephew became aware that a number of consoles of the VERSAJET II System contain a component whose lead (Pb) content may exceed the limit set in the RoHS Directive. The component in question is sealed inside the affected consoles, and does not come into contact with patients and/or with users.

Smith & Nephew is taking the necessary corrective actions to bring the VERSAJET II System consoles into conformity with the RoHS Directive. To that end, the following actions are being initiated:

1. Voluntary non safety related removal of the affected consoles from the market; and
2. Replacing affected consoles for a compliant system or issuing credit to customers.

For avoidance of doubt, based on our safety assessment, the non-RoHS compliant bearing does not present any safety concerns for patients or end-users of the consoles.

RoHS compliance is also required to complete the necessary conformity assessment procedure for the VERSAJET system.

This FSCA is being reported to the relevant Competent Authorities.

Context and reasons for this FSCA

Substance restrictions under the RoHS Directive have been made applicable to certain medical devices. Applicable medical devices manufactured and placed on the market after 22 July 2014 must be compliant with the restrictions regarding the use of hazardous substances set forth in the RoHS Directive.

Information relating to patient safety

As noted above, this issue does not present any safety concerns for patients or end-users of the consoles.

Actions to be taken by the user

1. Please quarantine any affected consoles in your possession and make arrangements with your supplier or Smith & Nephew representative to return the consoles for replacement or credit. Do not dispose of any affected consoles into the environment.
2. Complete the return slip and forward it to your national Smith & Nephew agency / distributor to confirm receipt of this Field Safety Notice.
3. Ensure this information is passed on to all those who need to be aware of it within your organization.
4. Maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Affected Products

This FSCA is applicable to the following products shipped 22Jul2014 – 31Oct2016:

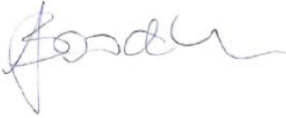
Product Description	Product Code	Serial Numbers
VERSAJET[®] II Hydrosurgery System Console	66800039	KWHB150029, KWHC150005, KWHC150009, KWHD150024, KWHD150028, KWHD150029, KWHD150032, KWHD150033, KWHD150037, KWHD150038, KWHE150017, KWHE150018, KWHE150019, KWHE150020, KWHE150021, KWHE150024, KWHE150027, KWHE150028, KWHE150030, KWHE150031, KWHF140047, KWHF140048, KWHF140049, KWHF140050, KWHF140051, KWHF140052, KWHF140053, KWHF140054, KWHF140055, KWHF140056, KWHF140057, KWHF140058, KWHF140059, KWHF140060, KWHF140061, KWHF140062, KWHK140033, KWHK140034, KWHK140035, KWHK140037, KWHK140038, KWHL140002, KWHL140003, KWHL140004, KWHL140006, KWHL140007, KWHL140008, KWHG150078

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Smith & Nephew is committed to distributing only products of the highest quality standards and to providing support to surgeons who use those products.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Foster', written in a cursive style.

Smith & Nephew Medical Ltd.

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If you have any questions please feel free to contact us under the following contact details:

Smith & Nephew Advanced Surgical Devices UK & I
Email: greg.williams@smith-nephew.com
Fax: + 44 (0)1480 423 201.

Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.

We hereby confirm that we are aware of this Field Safety Notice concerning the VersaJet[®] II Hydrosurgery System Console. The Field Safety Notice was communicated within our organization.

Please mark accordingly:

- In our facility we do not have any of the affected product in stock
or
 We will return the following products:

Product Code	Description	Serial Numbers to be Returned	Total Quantity to be Returned
66800039	VERSAJET [®] II Hydrosurgery System Console		

Institution: _____ Reference: WR-2017-01

Name: _____ Date/Signature: _____